Rec'd in DMS
7/25/01 H.lc

McNeil

McNeil Consumer Healthcare, 7050 Camp Hill Road, Fort Washington, PA 19034-2299 (215) 273-7000

JUL 2 4 2001

Docket No. 98N-0337
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Application for Exemption from 21CFR201.66
Request for Deferral of Compliance Time

Dear Sir or Madam:

McNeil Consumer Healthcare currently markets Extra Strength Tylenol® PM Caplets in a 10 count polypropylene vial with a polypropylene child-resistant safety closure. McNeil has been marketing this shelf keeping unit (SKU) for approximately 4 years. Our current labeling text is provided as Attachment 1.

Due to the limited amount of space that is available for labeling on this SKU, we have developed a wrap-around label to accommodate implementation of ***Drug Facts*** on this product. The labeling text in wrap-around format is provided as Attachment 2. This text wraps completely around the vial and pulls out so the consumer can read all of the labeling information.

Actual use of this labeling on the Tylenol PM vial may require additional compliance time for implementation. Therefore, we are submitting this request for additional time (8 months) beyond the May 16, 2002 compliance deadline to ensure that we can acquire, install, and validate the equipment that is necessary to produce, on a reliable, repetitive basis, a "compliant" vial package. The label and equipment are innovative technologies and they require sufficient development time to master the interface between equipment and material.

As the agency is undoubtedly aware, activities involving package design, equipment design and acquisition, and packaging line validation expend considerable resources. Based on our company's historical experience in designing and implementing new packaging options, the timeline for implementation of the wrap-around label follows:

98N-0337

APP29

Activity	Timing
Develop equipment specifications	2nd Quarter 2001
Order and build equipment	3rd & 4th Quarter 2001
Obtain equipment	4th Quarter 2001
Install and validate equipment	1st Quarter 2002
Finalize label specifications	1st Quarter 2002
Line testing and resolution of potential equipment issues	2nd Quarter 2002
Packaging validation	3rd Quarter 2002
Initiate production	4th Quarter 2002
Start to ship	4th Quarter 2002

The timeline for this project is based on FDA approval of the wrap-around vial label submitted as a pre-Approval SNDA under NDA 19-012. If label design modifications are requested, additional time, beyond December 16, 2002, may be required to implement.

We would appreciate your review of this deferral request for additional compliance time. If there are any questions, please contact me at 215-273-7878, or in my absence, Jackie Linse at 215-273-8733.

Very truly yours,

McNEIL CONSUMER HEALTHCARE

Paula J. Oliver

Paula J. Oliver
Senior Director
Regulatory Affairs

cc: (Letter only) C. Ganley, MD (HFD-560)
W. Ellenberg, Ph.D. (HFD-560)

Attachments

P:\PJO0653